JUL 1 5 2004

K041148

510(k) Summary
for
POCone Infrared Spectrophotometer

1. SPONSOR

Otsuka Pharmaceutical Co., Ltd.
2-9, Kanda Tsukasa-cho, Chiyoda-ku
Tokyo 101-8535 Japan

Contact Person:
Japan: Hideji Nonomura
Telephone: 81-88-665-2126

U.S.: Kyoko Tsuchiya
Telephone: 720-479-6449

Date Prepared: April 30, 2004

2. DEVICE NAME

Proprietary Name:	POCone Infrared Spectrophotometer
Common/Usual Name:	Infrared Spectrophotometer
Classification Name:	Colorimeter, Photometer, or Spectrophotometer for Clinical Use

For use of the POCone Infrared Spectrophotometer in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection, the following are also applicable:

Common/Usual Name:	Analysis System for Use with ^{13}C-Urea Breath Test
Classification Name:	Urea Breath Test

3. PREDICATE DEVICE

- UBiT-IR300 Infrared Spectrophotometer
  Otsuka Pharmaceutical Co., Ltd.
  K013371

4. DEVICE DESCRIPTION

The POCone Infrared Spectrophotometer is a compact analyzer designed for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori*. The POCone measures absorption of breath gas by calculating the ratios of $^{13}CO_2/^{12}CO_2$ for a reference breath gas and a sample breath gas. The difference between the ratios for the reference and sample breath gases is calculated to obtain the final measurement result, which is reported as $\Delta^{13}CO_2$ and expressed as delta per mil (‰) or Delta Over Baseline (DOB).

5. INTENDED USE

The POCone Infrared Spectrophotometer is an in vitro diagnostic device designed to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis.

The POCone Infrared Spectrophotometer is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The POCone Infrared Spectrophotometer is suitable for use in both point of care and clinical laboratory settings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Both the POCone Infrared Spectrophotometer and the UBiT-IR300 Infrared Spectrophotometer are general purpose instruments that are intended to measure changes in $^{13}CO_2$ content in breath CO_2 and have many potential applications. One of the applications for these systems is for use with commercially available ^{13}C-urea breath tests (^{13}C-UBT) for *H. pylori*. Meretek ^{13}C-urea breath tests can be used in conjunction with either instrument and the required breath samples collected for analysis. The POCone and UBiT-IR300 use the same breath collection bags that subjects blow into for collection of the breath samples.

The POCone and UBiT-IR300 are both infrared spectrophotometers and utilize the same principle of measurement to analyze $^{13}CO_2$ enrichment in breath samples. Both instruments are intended for use in point of care and clinical laboratory settings. The major differences between the POCone Infrared Spectrophotometer and the UBiT-IR300 Infrared Spectrophotometer are that the POCone offers increased portability and decreased sample measurement times.

7. PERFORMANCE TESTING

7.1 Nonclinical Testing

The POCone Infrared Spectrophotometer was tested to and complies with applicable requirements of IEC 60601-1 and IEC 60601-1-2.

Reproducibility and carryover studies were conducted using the POCone. These studies demonstrated that the POCone performs according to its specifications and that there is negligible carryover and inter-device variability.

7.2 Clinical Testing

A clinical study was conducted to evaluate the performance of the POCone Infrared Spectrophotometer to measure changes in $^{13}CO_2$ content in breath CO_2 gas by infrared spectroscopic analysis. The multi-center, prospective study was designed to compare the POCone Infrared Spectrophotometer for measuring $^{13}CO_2$ enrichment in breath with the UBiT-IR300 Infrared Spectrophotometer. Subjects were recruited from five Physician Office Laboratory (POL)/Point of Care (POC) settings. Subjects underwent a standard urea breath test (UBT) which is used for the detection of *Helicobacter pylori* (*H. pylori*) infection. Analyses of breath samples were performed using both the POCone and UBiT-IR300 methods. The number of evaluable subjects was 220 across all participating sites.

The primary endpoint was the percent agreement of the POCone results as compared to the UBiT-IR300 results using a cut-off value of 2.4 Delta Over Baseline (DOB). The percent agreement for all subjects is as follows:

% Overall Agreement:	99.55%	[95% CI: (97.67, 99.98)]
% Positive Agreement:	100.00%	[95% CI: (95.90, 100.00)]
% Negative Agreement:	99.25%	[95% CI: (96.27, 99.96)]

As a secondary endpoint, paired Delta Over Baseline (DOB) values were analyzed directly in order to determine the extent to which the methods were linearly related and the degree to which they were correlated. Comparison of the paired DOB values demonstrates that the two methods give results which are very highly correlated ($r > .99$) and appear to be linearly related to one another. The data suggest that the regression lines pass through the origin with a slope very near one.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 1 5 2004

Otsuka Pharmaceutical Co., Ltd.
c/o Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: k041148
Trade/Device Name: POCone Infrared Spectrophotometer
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: MSQ, JJQ
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

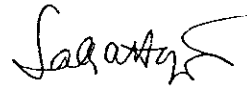
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041148

Device Name: POCone Infrared Spectrophotometer

Indications for Use:

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The POCone Infrared Spectrophotometer is intended for use in conjunction with commercially available Meretek ^{13}C-urea breath tests for the detection of *Helicobacter pylori* (*H. pylori*) infection. The POCone Infrared Spectrophotometer is suitable for use in both point of care and clinical laboratory settings.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041148